

Conditions of Use Under TSCA Sections 5 and 6

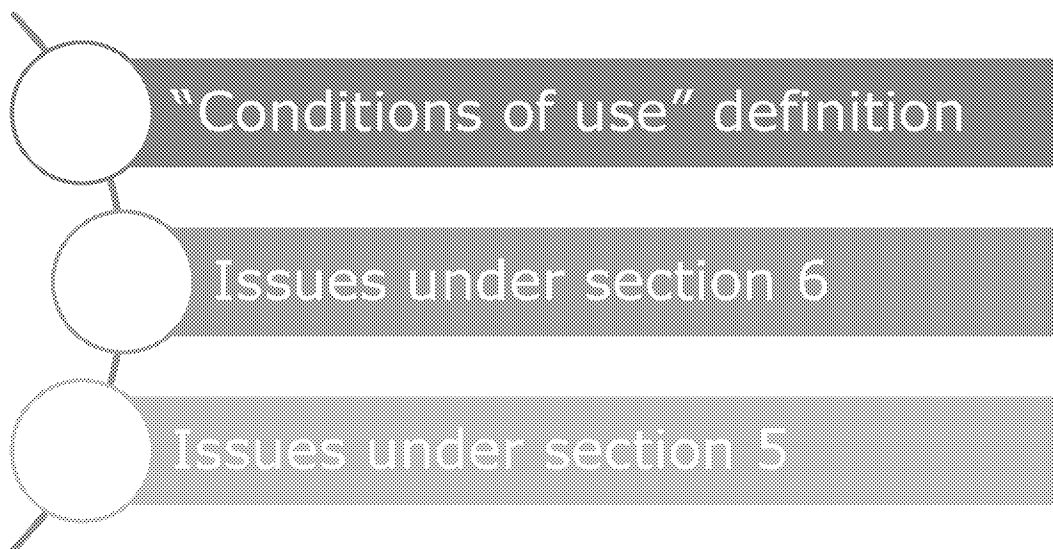
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Overview



"Conditions of use"

EPA must
decide whether
a chemical
substance

"may present" /

"is not likely to
present" /

"presents" /

"does not
present" –

- **"an unreasonable risk** of injury to health or environment,
- without consideration of costs or other nonrisk factors,
- including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator
- **under the conditions of use."**

"Conditions of use"

TSCA § 3(4):

- "The term 'conditions of use' means the circumstances, **as determined by the Administrator**, under which a chemical substance is **intended**, known, or **reasonably foreseen** to be manufactured, processed, distributed in commerce, used, or disposed of."
- Chemical-specific, not generic

In making decisions under sections 5 and 6:

- EPA has discretion to select among conditions of use
- But some NGOs maintain that EPA must consider all conditions of use

Scope of a risk evaluation

§ 6(b)(4)(D) – Scope

- “The Administrator shall, not later than 6 months after the initiation of a risk evaluation, publish **the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use,** and the potentially exposed or susceptible subpopulations **the Administrator expects to consider**”.
- Scope determines scope of risk determination, risk management, and preemption

Content of a risk evaluation

§ 6(b)(4)(F)(ii) – a
final risk evaluation
must:

“describe **whether
aggregate or sentinel
exposures** to a chemical
substance under the
conditions of use **were
considered**, and the basis
for that consideration”

Legislative history

Senator Vitter (June 6, 2016 Cong. Rec.):

- "The Agency is well aware that some categories of uses pose greater potential for exposure than others and that the risks from many categories of uses are deemed negligible or already well controlled."
- **"The Agency is given the discretion** to determine the conditions of use that the Agency will address in its evaluation of the priority chemical."

EPA discretion – section 6

Proposed risk evaluation rule (Jan. 19, 2017)

Proposed 40 C.F.R. § 702.39(c)(1) re scope:

- “EPA will identify those uses that constitute the conditions of use that will be assessed during the risk evaluation. **Those uses shall be all circumstances** under which the Agency determines that the chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.”

EPA discretion – section 6

Final risk evaluation rule, July 20, 2017:

- 40 C.F.R. § 702.41(c)(1): The scope of a risk evaluation will include “the condition(s) of use, **as determined by the Administrator**, that EPA plans to consider in the risk evaluation.”

Preamble – EPA has discretion, e.g.:

- May exclude impurities – 1,4-dioxane
- May exclude legacy uses and related disposal – asbestos
- But EPA will always include “an evaluation of the conditions of use that raise greatest potential for risk.”

EPA needs discretion

Preamble:

"EPA's overall objective of this rule is to ensure that it is able to focus on conducting a **timely, relevant, high-quality, and scientifically credible** evaluation of a chemical substance as a whole EPA wants also to ensure that the Agency can effectively assess, and where necessary, regulate chemical substances, **within the statutory deadlines.**"

NGO challenges

Consolidated NGO petitions for review of risk evaluation rule & prioritization rule (9th Cir.)

- NRDC, Earthjustice, EWG, Sierra Club, others
- ACC and other trade associations have intervened

Expected main issue for risk evaluation challenge: scope of risk evaluations

- Briefing to be completed by June 2018

PMNs and conditions of use

Similar issue – in deciding whether a PMN substance “may present”/“is not likely to present” an unreasonable risk, which conditions of use must EPA consider?

- Those described in the PMN
- “Reasonably foreseen” uses from PMN
- “Reasonably foreseen” uses of future manufacturers and processors of the PMN substance once added to the Inventory?

Affects section 5(e) orders, SNURs

Conditions of use in a PMN

Risk is a function of hazard and exposure

If EPA makes a "may present" finding:

- Remedy – section 5(e) order to restrict exposure
- Mandatory for PMN submitter

Possible SNUR for future manufacturers and processors

“Not likely to present”?

EPA has mostly made that finding solely on basis of low hazard (regardless of conditions of use)

EPA should also make that finding based on hazard + low exposure concern (taking PMN's conditions of use into account)

- Where PMN does not raise exposure concerns (e.g., release to water, respirator)
- Where PMN raises exposure concerns, but is amended to address them

"Reasonably foreseen" uses from PMN's conditions of use

NGOs: It is "reasonably foreseen" that PMN submitter will not follow PMN's exposure controls after NOC, creating need for "may present" determination

Is a PMN (or an amended PMN) binding?

- NGOs and EPA: no
- Certification statement
- "Binding option"?

Section 5(e) order would clearly be binding

But not "necessary to protect against an unreasonable risk"

Future manufacturers and processors after NOC filed

Is the PMN substance “likely to present” solely because of potential conditions of use of future manufacturers and processors?

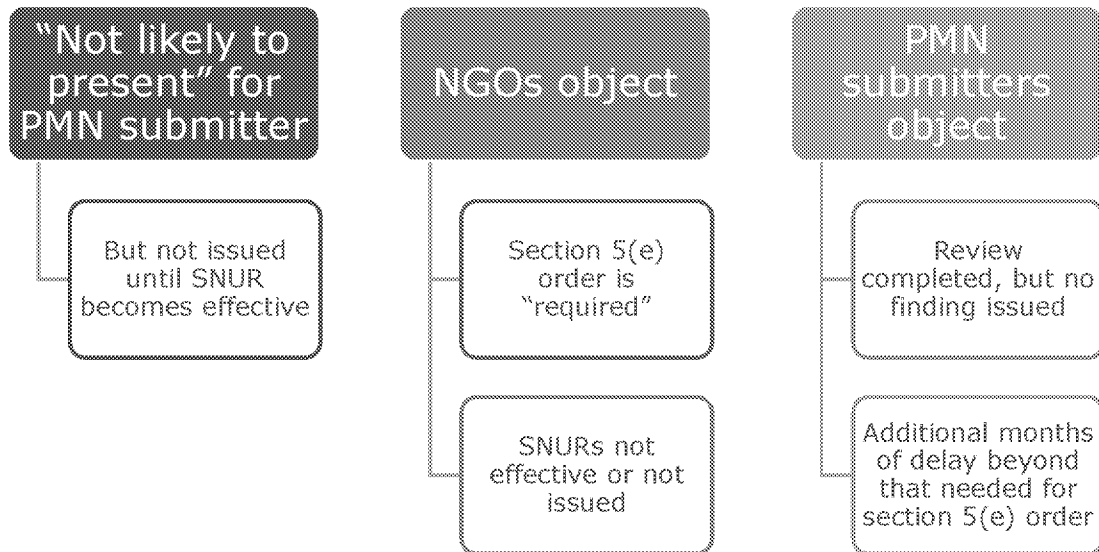
Remedy: section 5(e) order

- The order would affect only the PMN submitter
- Future manufacturers and processors would not be parties to the order

SNUR factors:

- EPA must consider “reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance”

EPA's planned non-order SNUR



Better non-order SNUR

EPA should issue "not likely to present" upon completion of review of PMN (or amended PMN)

- Binding option?
- PMN submitter can file NOC

Issue SNUR expeditiously to address conditions of use of possible future manufacturers and processors (and PMN submitter)

- Virtually no problems in > 30 years of PMN submitter or other manufacturers or processors making intended new use "ongoing" after NOC

NGO challenge

NRDC
petition for
review of
PMN
"framework
document"

ACC, NAM,
Safer
Chemicals-
Healthy
Families
have
intervened

No briefing
schedule yet

Questions?



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